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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/990,537	11/16/2001	Oskar Axelsson	NIDN-10428	2564
36335	7590	02/24/2004	EXAMINER TUCKER, ZACHARY C	
AMERSHAM HEALTH IP DEPARTMENT 101 CARNEGIE CENTER PRINCETON, NJ 08540-6231			ART UNIT 1624	PAPER NUMBER

DATE MAILED: 02/24/2004

*Kj*

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Applicati n No.

09/990,537

Applicant(s)

AXELSSON ET AL.

Examiner

Zachary C. Tucker

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-12 and 14-18 is/are pending in the application.
- 4a) Of the above claim(s) 8-12 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7 and 14-18 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 November 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- |  |  |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)            |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>16Nov01</u> . | 6) <input type="checkbox"/> Other: ____  |

**DETAILED ACTION**

***Election/Restrictions***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-7 and 14-18, drawn to a process for the preparation of an MR contrast agent, classified in classes 424/9.3 and 560/231.
- II. Claims 8-12, drawn to a hydrogenation apparatus, classified in class 422/129.

Inventions I and II are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case both 1 and 2 are true. The process of claims 1-7 does not necessarily have to be conducted in the claimed apparatus. The claimed apparatus is not restricted in its utility to only the manufacture of MR contrast agents. Lastly, inventions I and II are separately classified, which is indicative of an undue search burden on the examiner, should both inventions be searched.

During a telephone conversation with Robert Chisholm on 13 February 2004, a provisional election was made without traverse to prosecute the invention of Group I, claims 1-7 and 14-18. Affirmation of this election must be made by applicant in replying to this Office action. Claims 8-12 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1-7 and 14-18 are rejected under 35 U.S.C. 102(e) as being anticipated by US 6,574,495 B1 (Golman et al). The inventive entity of the Golman et al patent is different from that of the instant application, therefore, invention was "by another." The Golman et al patent claims domestic priority under 35 U.S.C. 119(e) to two provisional applications, 60/066,570 (filed 26 November 1997) and 60/076,924 (filed 5 March 1998), both with filing dates prior to the foreign priority date of the instant application.

Golman et al discloses a method for making MR contrast agents by reacting a hydrogenatable MR imaging agent precursor with para-hydrogen enriched hydrogen. The precursors employed in Golman et al's method are unsaturated compounds, with

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carbon-carbon double or triple bonds. Specifically preferred precursors are described in column 7, lines 10-40.

Column 14, lines 50-67 – column 15, lines 1-67 and the first two lines of column 16 in the Golman et al patent describe the process of claims 1 and 15. The solution of precursor compound, is introduced into the hydrogenation chamber, into a particulate bed (which contains a heterogeneous hydrogenation catalyst) through which the enriched hydrogen is injected and is flowing upwardly. This gas-liquid countercurrent flow, through a particulate bed, necessitates some droplet formation. To the extent that some droplets of precursor compound will form in the hydrogenation reactor, limitations of instant claim 1, part ii are met.

Limitations specified in claims 14 and 2-4 (and in optional part iii of instant claim 1), are disclosed in column 13, lines 4-13 of Golman et al. Golman et al teaches that hydrogenation with para-hydrogen enriched hydrogen is conducted in a very low magnetic field, preferably 0 to 1 $\mu$ T is highly desirable.

Column 13, lines 34-54 of Golman et al disclose an embodiment wherein both the substrate (the precursor as it is referred to in Golman et al) and catalyst are water-soluble, meeting the limitations of instant claim 7.

Claims 16-18 are included in this rejection under 35 U.S.C. 102(e) because they further limit a method step which is set forth as an optional element of the method of instant claim 1 (by way of claim 14), namely (iv), dissolving the imaging agent in an aqueous medium.

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Claims 5 and 6 are included in this rejection under 35 U.S.C. 102(e) because they further limit a method step (step iii) which is set forth as being optional, that is, not required.

**Conclusion**


Any inquiry concerning this communication should be directed to Zachary Tucker whose telephone number is (571) 272-0677. The examiner can normally be reached Monday-Friday from 6:30am to 3:00pm. If Attempts to reach the examiner are unsuccessful, the examiner's supervisor, Mukund Shah, can be reached at (571) 272-0674.

If you are unable to reach Dr. Shah within a 24 hour period, please contact James O. Wilson, Acting -SPE of 1624 at (571) 272-0661.

The fax number for the organization where this application or proceeding is assigned is (703) 308-4556 for regular communications and (703) 308-4242 for after-final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-2717.

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**JAMES O. WILSON**  
**SUPERVISORY PATENT EXAMINER**  
**TECHNOLOGY CENTER 1600**